DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 23, 2015

JJGC Industria e Comercio de Materiais Dentarios SA
c/o Mr. Christopher Klaczyk
Instradent USA
60 Minuteman Road
Andover, MA 01810

Re: K150182
Trade/Device Name: Neodent Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: March 23, 2015
Received: March 24, 2015

Dear Mr. Klaczyk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications For Use

510(k) Number (if known): K150182

Device Name: Neodent Implant System

Indications for Use:

The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.

Prescription Use_____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K150182

510(k) Summary

Submitter: Instradent USA, Inc. (on behalf of JJGC Indústria e Comércio de Materiais Dentários SA)
60 Minuteman Road
Andover, MA 01810
Registration No.: 3010593814
Owner/Operator No.: 10045493

Contact Person: Christopher Klaczyk
Acting Director of Regulatory Affairs
Tel.: (978) 747-2575

Date Prepared: April 23, 2015

Product Code(s): DZE, NHA

Device Class: II

Classification Panel: Dental

Classification Name: Endosseous dental implant (21 CFR 872.3640)

Proprietary Name: Neodent Implant System

Predicate Device(s):

- Neodent Implant System (K123022) CM Drive Implants; Primary predicate
- Neodent Implant System (K133592) Acqua Surface

Reference Device(s):

- Neodent Implant System (K101945) Titamax CM EX Implants
- Straumann Screw Retained Abutments (K141871)

Device Description: The subject Neodent Implant System implants are threaded, self-tapping, root form, endosseous dental implants with a Morse taper abutment interface. The proposed CM Drive implants come in three diameters (3.5, 4.3 and 5.0 mm) and a length of 18.0 mm. They are made of commercially pure titanium. They are available with the NeoPoros grit blasted

	and acid etched surface finish or the Acqua grit blasted, acid etched and hydrophilic, chemically active surface finish. The CM Drive implants (K123022) have been shown to be compatible with the previously cleared angled abutments (K101945) having the CM implant-to-abutment interface. The addition of the 18mm lengths to the previously cleared CM Drive Implants has no detrimental impact on device indications or performance. All other attributes are identical. No modifications were made to the coronal features of the implant that would impact dynamic fatigue performance. A groove has been added to the conic portion of six (6) CM Mini Conical Abutments to ensure that the abutments do not release from the transfer tool during transfer from the package until secured in the implant. This feature also assures secure retention of the abutment in the package during storage and shipment. The pilot hole depth of the CM Abutments was reduced in order to increase the minimum wall thickness of the abutment. The length of the internally threaded portion of the abutment was not changed, so engagement between the occlusal screw and the abutment is also unchanged.
Intended Use:	The Neodent Implant System is intended to be surgically placed in the bone of the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, to restore chewing function. It may be used with single-stage or two-stage procedures, for single or multiple unit restorations, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading.
Materials:	The subject devices are produced from commercially pure titanium conforming to ASTM F67. This is the same material as for the predicate devices cleared to market per premarket notification submission K123022.
Technological Characteristics:	The proposed Neodent Implant System – CM Drive Implants are manufactured using precision machining systems from solid material (i.e. one-piece construction). All technological characteristics of the subject devices are the same as for the predicate devices, as shown in the table below.

Feature	Subject Devices CM Drive Implants K150182	Predicate Devices CM Drive Implants K123022 & K133592	Comparison Summary
Implant-to-Abutment Connection	Morse Taper	Morse Taper	Same
Diameter(s)	3.5, 4.3 & 5.0 mm	3.5, 4.3 & 5.0 mm	Same
Length(s)	18 mm	8, 10, 11.5, 13 & 16 mm	Similar to reference device K101945
Material	Commercially pure titanium, Grade 4	Commercially pure titanium, Grade 4	Same
Primary Package	Styrene-butadiene copolymer vial with a polystyrene and thermoplastic elastomer cap contained within a PET tray and sealed with a Tyvek lid	Styrene-butadiene copolymer vial with a polystyrene and thermoplastic elastomer cap contained within a PET tray and sealed with a Tyvek lid	Same
Sterilization	Gamma irradiation, 25 kGy min.	Gamma irradiation, 25 kGy min.	Same
Dynamic Fatigue Test Configuration	30º Universal CM Exact Abutment	No test data submitted – limited to straight abutments	Similar to reference device K101945

Performance Data: Per *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments* dated May 12, 2004, the substantial equivalence of the subject device(s) are satisfactorily addressed via bench studies. Dynamic fatigue test data consistent with FDA guidance and ISO 14801 have been referenced in support of this submission.

The load-bearing features of the implant-abutment connection were tested in conjunction with angled prosthetic abutments representative of the worst-case scenario. The results of the fatigue load testing demonstrate that the subject devices are substantially equivalent to the predicate devices.

A risk analysis in the form of a Failure Modes and Effect Analysis was conducted to assess substantial equivalence of the submission device with respect to the changes to the device and labeling. FMEA demonstrated sterility, packaging, and biocompatibility assessments for the predicate and reference devices are also applicable to the subject devices.

Summary: The primary modification of the subject device is addition of an 18mm length for the device system CM Drive implants, cleared in K123022 (primary predicate) and K133592. While the subject CM Drive implants having 18 mm length exceed the range of previously cleared lengths for predicate devices, the previously cleared reference predicate Titamax CM EX (K101945) series includes implants with length of 19mm.

Conclusions: The subject device and the predicated devices have the same intended use, have similar technological characteristics, identical material composition and encompass a very similar or the exact same range of physical dimensions, including diameter and length of the implants and Implant to Abutment connection and sterilization.Based upon our assessment of the design and applicable performance data, the subject devices have been determined to be substantially equivalent to the identified predicate devices.